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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,150	11/13/2001	He Wei-Wu	Origen 1-C1	6524
23599	7590	06/15/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			LU, FRANK WEI MIN	
		ART UNIT	PAPER NUMBER	
			1634	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

*jm*

## Office Action Summary

Application No.	WEI-WU ET AL.
09/987,150	
Examiner	Art Unit
Frank W Lu	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 13 November 2001.  
2a) This action is FINAL.                            2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 1-10 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/2003.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation “the same gene” in the claim. There is insufficient antecedent basis for this limitation in the claim since it is unclear which gene means the same gene and there is no word “gene” before the phrase “the same gene”. Please clarify.

4. Claim 1 is rejected as vague and indefinite in view of “at least one representative of each of said independent DNA clones”. Since the phrase “each of said independent DNA clones” means one clone which is narrower than at least one representative clone (one or more), it is unclear what means “at least one representative of each of said independent DNA clones”. Please clarify.

5. Claim 1 is rejected as vague and indefinite because it is unclear that “at least one clone” in the amplifying step is from the independent DNA clones of the pooling step or not. Please clarify.

6. Claims 7 and 9 are rejected as vague and indefinite. Since the presence of same sized DNA product in a plurality of pools does not mean that the DNA clone is full-length gene, it is unclear what means “the presence of same-sized DNA product in a plurality of pools indicates the presence of a DNA clone representing a full-length or a specific transcript of said gene”. Please clarify.

7. Claims 8 and 10 are rejected as vague and indefinite in view of the phrase "a second primer" since there is no phrase "a first primer" in claims 1 and 2. Please clarify.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Bergsma *et al.*, (US Patent No.6,187,544 B1, priority date: June 4, 1997).

Note that this rejection was made in view of the ambiguity of claims 1 and 7-10 (see above the rejections under 35 USC 112).

Bergsma *et al.*, teach rapid cloning of full-length cDNAs using clone arrays from cDNA libraries. They teach to construct four cDNA sub-libraries from a tissue source which have different insert sizes; e.g., 1)>6 kb insert size, 2) 3 to 6 kb insert size, 3) 1.5 to 3 kb, and 4) 0.6 to 1.5 kb. Before size selected cDNA sub-libraries are made, they are pre-enriched for mRNA 5' sequences. These size fractionated cDNA clones are then arranged into a 96 well microtiter dish such that 30 clones from a specific insert size pool (sub-library) are placed into each of the wells. A total of 384 microtiter dishes are thus prepared for a total of  $1.105 \times 10^6$  clones per four sub-libraries (see column 2, third paragraph).

Regarding claims 1-6 and 10, since Bergsma *et al.*, teach pool samples from 12 columns (12 column pools) and 8 row (8 row pools) for each 96 well plate for a total of 20 pools (see the method B in Figure 2 and column 6, lines 4-41), Bergsma *et al.*, disclose pooling samples from a plurality of wells of a multi-well plate (ie., a 96 well plate) to form a plurality of pools (ie., 20 pools) wherein said multi-well plate comprising a plurality of individual wells in rows and column as recited in claim 1, said pools are formed by pooling samples from a plurality of wells in a column and/or a row as recited in claim 2, each pool is formed by pooling samples from each well in a column of wells and each well in a row of wells as recited in claim 3, said multi-well plate is a 96-well plate, comprising 8 rows, with 12 wells in each row and 12 columns, with 8 wells in each column as recited in claim 4, each pool is formed by pooling samples from each well in a column and each well in a row, whereby 20 pools are thus formed as recited in claim 5. Since Begsma *et al.*, teach that each of the wells in a 96 well plate has m number of clones wherein m is from 1 to 2000 (see column 3, lines 13-46), a 96 well plate has 96 to 192,000 clones. When m equals 100, a 96 well plate has 9,600 clones. Therefore, Bergsma *et al.*, teach that each well comprising at least one representative (ie., 100 clones) of 4,000-12,000 independent DNA clones (ie., 9,600 independent DNA clones per 96 well plate) and wherein each said sample (ie., 100 clones in a well) comprises at least one representative of each of said independent DNA clones as recited in claim 1. Since Bergsma *et al.*, teach that the row and column DNA pools for each tissue library are analyzed for the presence of a specific DNA segment by PCR (polymerase chain reaction) (see column 2, third paragraph) using a primer that is complementary to the 5' end of cDNA interest and another primer that is complementary

to the library vector (see column 7, third paragraph), Bergsma *et al.*, disclose amplifying DNA clones in each pool by polymerase chain reaction using nucleic acid primers to form amplified DNA product, wherein at least one primer is specific for a gene present in at least one DNA clone from said independent DNA clones as recited in claim 1 wherein another primer is a vector-specific primer and said DNA clones further comprise vector DNA as recited in claim 10. Since Bergsma *et al.*, teach that PCR products are separated by gel electrophoresis and detected by ethidium bromide staining to identify the multi-plate row and column DNA pools generating the appropriate PCR product and row and column identification allows for the concomitant identification of both the original insert size fraction pool and the single plate pool yielding the appropriate PCR product, and further identifying the specific well containing the corresponding full length clone (see column 2, third paragraph), Bergsma *et al.*, disclose detecting amplifying DNA product from a plurality of said pools (ie., 20 pools) and identifying the size of a DNA clone in a pool which is representative of said gene or the presence of multiple different DNA clones in a plurality of pools which are representative of multiple different transcripts originating from said gene as recited in claim 1 wherein said detecting amplified DNA product is performed by gel electrophoresis as recited in claim 6.

Regarding claim 8, since Bergsma *et al.*, teach both primers for the PCR can be from the cDNA of interest (see column 8, claims 5 and 7), claim 8 is anticipated by Bergsma *et al.*.

Regarding claims 7 and 9, Bergsma *et al.*, teach row and column identification (ie., PCR) allows for the concomitant identification of both the original insert size fraction pool and the single plate pool yielding the appropriate PCR product, and PCR is

then performed on row and column pools derived from the positively identified 96 well plates having the largest cDNA insert size, Bergsma *et al.*, disclose said identifying (ie., PCR) is comparing the sizes of DNA product detected in each pool (ie., obtaining the largest cDNA insert size), and determining pools of wells or columns which contain DNA product having the same size (ie., , PCR original insert size fraction pool) whereby the presence of same-sized DNA product in a plurality of pools indicates the presence of a DNA clone representing a specific transcript of said gene (ie., a specific cDNA) as recited in claims 7 and 9,

Therefore, Bergsma *et al.*, teach all limitations recited in claims 1-10.

### ***Conclusion***

10. No claim is allowed.
11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu  
PSA

June 10, 2004

**FRANK LU**  
**PATENT EXAMINER**